

Proposed Pilot Initiative for an Arizona Clinical Research Consortium

Background

The Arizona Clinical Research Consortium (the ACRC) is an outgrowth of a statewide effort sponsored by the Arizona Biomedical Research Commission and the Flinn Foundation to develop a new model of translational research in Arizona to strengthen the state's position in the national biosciences. This effort, known as the "Arizona Translational Research Pathway Project," involves experts from universities, research institutes, teaching hospitals, medical centers, law, bioscience industry and government.

In June 2006, the Arizona Translational Research Pathway Project announced the concept of an Arizona Translational Resource Network (AzTransNet) to support developing collaborative clinical research activities in Arizona. AzTransNet seeks to support a variety of collaborative clinical research activities, including:

- Creation of an **Institutional Review Board (IRB) Networking Forum** to raise awareness of issues, foster collaborations and create a sense of community and trust.
- Institution of **Technical Policy Development Retreats** that focus on specific policy and supporting document needs of IRBs.
- Advancement of **guidelines** on approaches to complex business practices that can pose barriers to collaboration in biomedical research, such as indemnification, intellectual property, cost sharing, and credentialing.
- Development of a **community-based participatory research guide** for advancing collaborations with Native American and Hispanic/Latino population groups.
- Establishment of an **Arizona Community Institutional Review Board** to provide IRB support for independent research sites that lack in-house IRBs and studies that span multiple research sites.

This document discusses one of those collaborative efforts: the Arizona Clinical Research Consortium.

The Purpose of the Arizona Clinical Research Consortium

The Arizona Clinical Research Consortium (ACRC) pilot initiative is designed to increase the involvement of community physicians in clinical research. Through involving more community physicians in clinical research, the ACRC hopes to:

- Provide more Arizona residents with access to clinical trials at a time critical to their particular disease states.
- Give Arizona research institutions more clout in the clinical trial marketplace by increasing the ability of Arizona institutions to recruit patients for clinical trials

and by reducing the time from first contact to first enrollment. Quicker enrollment promises to lead to increased clinical research funding and better pricing and other terms in research contracts with sponsors from the pharmaceutical and medical device industries.

- Make Arizona a more attractive location for clinical researchers to locate, by creating a system of outreach and support for clinical trials, including leveraging Arizona's growing patient population to be a major center for recruitment in clinical trials across all phases.

To ensure a wide perspective, the ACRC organizing committee has spoken with individuals across the country who spearheaded collaborative clinical research activities in their communities, and involved all interested institutions in Arizona. After this research and discussion, we arrived at a recommendation to design a pilot effort—the creation of the Arizona Clinical Research Consortium. A description of the proposed ACRC and identified next steps to advance this pilot initiative follow.

Organizing the Arizona Clinical Research Consortium

To best advance collaborative clinical research activities, we recommend a consortium approach with centralized efforts focused on coordination, facilitation and awareness building. The centralized efforts will be directed at increasing the ability of Arizona institutions to recruit more patients for clinical trials and reducing the time from first contact by a research sponsor to first enrollment of patients in the trial. The conduct of particular clinical trials will be retained at the institutional level.

Membership in the consortium will be open to all institutions supporting principal investigator clinical research teams, such as universities, non-profit research organizations, hospitals and medical centers, and medical groups.

Activities of the Arizona Clinical Research Consortium

Community Physician Outreach: The Consortium will create a framework for conducting outreach to community physicians to get physicians involved in clinical research. Community physicians are an essential element in identifying patients early for enrollment in clinical trials.

Each Consortium “team” will be chaired by a principal investigator who is a specialist in a particular disease area and who has contacts to pharmaceutical companies, medical device companies or other funding sources for clinical trials. The Consortium team will identify community physicians treating patients who might be appropriate candidates for inclusion in a particular clinical trial. The Consortium will then arrange outreach to these community physicians.

The role of the community physician in the clinical trial would vary depending on the complexity of the procedures to be performed in the trial. For complex-procedure trials (such as where advanced equipment is necessary and available only at the primary

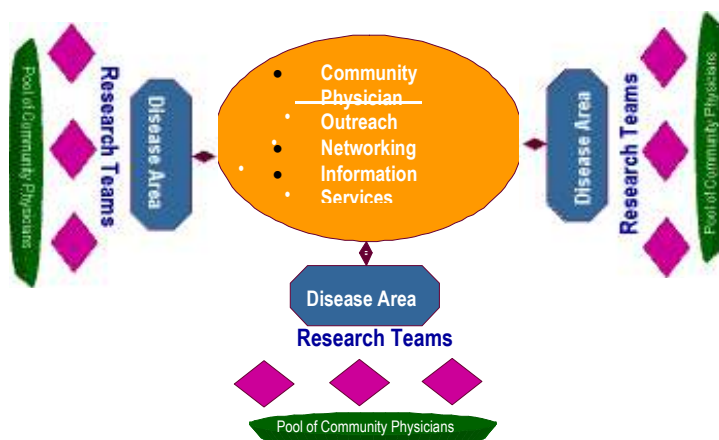
clinical trial site), the community physicians would be involved in identifying and screening patients for inclusion and obtaining the initial informed consent from the patient. For clinical trials where advanced equipment or specialized training was not required, the community physicians would perform parts or all of the clinical trial procedures and report findings to the primary clinical trial site.

Networking: The Consortium would also host quarterly meetings for groups of investigators and community physician—by targeted disease areas—to establish a sense of community, review results of recent clinical research activities, introduce ongoing and new clinical research protocols, and discuss methods of cooperation in clinical trials.

Information Services: The Consortium would develop up-to-date information services on ongoing clinical trials designed to reach principal investigators, community physicians, clinical research coordinators, and institutional research directors. If feasible, the Consortium might also develop a Web site or other methods of public outreach about clinical trials in Arizona.

Other Collaborative Efforts: The Consortium may identify other collaborative activities as desired by the members.

The figure below depicts the concept of an Arizona Clinical Research Consortium:



Keys to Success of the Arizona Clinical Research Consortium

Addressing the needs of physicians: We anticipate that private practice physicians will be interested in participating in order to have an opportunity to affiliate with centers of excellence. This will allow community physicians to meet and work with subspecialty research leaders in their field of interest and to provide cutting-edge care to their patients through participation in clinical trials. It also will provide private practice physicians with new sources of revenue by participating in the clinical trials. At the same time, the Consortium needs to address the concerns of private physicians that they not lose their

patients to specialized centers of clinical research by developing protocols in which the community physicians maintain their relationships with these patients during and after completion of a clinical study.

Addressing the needs of hospitals and other research institutions: The Consortium model should increase the opportunities for multiple institutional research sites in Arizona to enroll patients in particular clinical research trials. A more efficient process to enroll multiple patients translates into higher indirect rates for clinical trials and reduced administrative burdens and costs to the institutions.

Addressing the needs of patients: Patients of course play a key role in the conduct of clinical trials. Providing outreach and education to patients about available clinical trials will empower patients and will provide another method of outreach to community physicians.

The Next Step -- Piloting the ACRC through Neurological Diseases

The organizing committee identified neurological diseases, such as Multiple Sclerosis, Alzheimer's Disease, Parkinson's Disease, Stroke and Pain, as likely first candidates for the Consortium model. We chose neurological diseases because they are a focus of the Biosciences Roadmap Platform, because organizations specializing in neurological diseases are interested in supporting these collaborative activities, and because a leading principal investigator in MS—Dr. Tim Vollmer at Barrow Neurological Institute—has volunteered to use this model as outreach to community physicians treating MS patients to increase enrollment in MS clinical trials. We expect that we could quickly include other disease areas, as well, such as diabetes and cardiology.

Conclusion

The Arizona Clinical Research Consortium is an exciting project designed to provide more Arizona residents with access to clinical trials at a time critical to their particular disease states, give Arizona research institutions more clout in the clinical trial marketplace by increasing the ability of Arizona institutions to recruit patients for clinical trials, and make Arizona a more attractive location for clinical researchers to locate.